

K060780

APR 6 2006

2. 510 (k) Summary

2.1. Common

2.1.1. Regulatory Code

21 CFR 886.1930

2.1.2. Company Name/Contact

510(k) owner/holder:

Ryazan State Instrument-Making Enterprise
32 Kalyaev St.
Ryazan, 390 000 Russia

Agent for Ryazan and Contact Person:

Boris Kun
Bicom, Inc.
151 East Walnut Street
Long Beach, NY 11561

phone: 516-431-3859
facsimile: 888-260-0606

2.1.3. Medical Specialty

Ophthalmic

2.1.4. Name of Device

Trade name:	Tonometer diaton
Common Name:	Tonometer and accessories subpart B - Diagnostic devices

2.1.5. Product Code

HKX

2.1.6. Device Class

Class II

2.1.7. Regulation Number

21 C.F.R. § 886.1930

2.1.8. Predicate Devices

Diaton is substantially equivalent to the following legally marketed devices:

Goldman Manual Tonometer (Golden Vision, Inc.)	510(k) Number: K981432
TGDc-01 "PRA" (Truevision Instruments)	510(k) Number: K021937

2.2. *Intended Use*

Quick and accurate measurement of IOP in various situations independent of place and time is the dream of every ophthalmologist. Today the portable tonometer diaton gives you that capability. This new IOP measuring method through the eyelid in the sclera area, unique to our device, eliminates completely any effect on the mucous eye membrane.

- ⑩ Painless diagnostics without anesthetics and antiseptics
- ⑩ Elimination of infection risk
- ⑩ Measuring results independent of cornea's crookedness
- ⑩ Evaluation of IOP in patients after any operations on cornea
- ⑩ IOP measurement in children
- ⑩ Monitoring of Glaucoma treatment

2.3. *Technological Characteristics*

Measurement range, mm Hg	5-60
The time of a single measurement, sec., not more	3
Autonomous power supply: feed element CR2032 "VARTA" or similar. Supply voltage, V	3
Number of measurements using one feed element, not less	1500
Serviceability, years	5
Weight, g, not more	89
Dimensions, mm, not more	173,5x25,5x19,5

2.4. Conclusion

The results of the comparison medical tests of Tonometer diaton and Goldmann tonometer demonstrated their **high coincidence degree** in the whole range with the compared devices. We achieved the same results from all devices.

Taking into account the comparison medical tests findings as well as tonometer diaton advantages (anesthetics and antiseptics are not necessary; elimination of infection risk; short-time measurement; results independent of cornea's crookedness) its wide application in ophthalmology is recommended alongside with Goldmann tonometer, especially while carrying out **mass examination of population**. Also, it is **recommended for use at home** to control ophthalmotonus condition **under drugs and medical treatment**.

Tonometer diaton represents an **improvement to existing technology** to ophthalmology. It is compact, handy, and can be easily **placed in a smock pocket or in a handbag**.

Portability, safety and simplicity make tonometer diaton ideal for a **wide range of application**:

- ⑩ for mass examination of the population
- ⑩ at the patient's bedside
- ⑩ in geriatrics homes
- ⑩ in children hospitals
- ⑩ at the army
- ⑩ at home.

Tonometer diaton is not only good for determining the potential for glaucoma onset. It can also be used for **monitoring treatment effectiveness throughout the day**. Unlike other Tonometers, diaton can be used **repeatedly during the day with no effect on the eye.**

Tonometer diaton is **easy to use**. A simple operating manual will be provided with each device. It takes only some seconds to measure the IOP, with the patient in a sitting or supine position. The IOP measurement is displayed on an LCD screen of the device. To test the tonometer's operational integrity there is a pressure control device provided.

Tonometer diaton uses the latest technologies, which provide it high reliability, quality and longevity.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 2006

Ryazan State Instrument-Making Enterprise
c/o Mr. Neil E. Devine Jr.
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
Twinsburg, OH 44087

Re: K060780

Trade/Device Name: Diaton Tonometer
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer & Accessories
Regulatory Class: Class II
Product Code: HKX
Dated: March 21, 2006
Received: March 22, 2006

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "MB Eydelman MD", with a stylized flourish at the end.

Malvina B. Eydelman, M.D.

Division Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: Diaton Tonometer

Indications for Use:

The Diaton Tonometer is intended to measure intraocular pressure (IOP). The device is intended for use as an aid in the diagnosis of glaucoma and for monitoring IOP.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Denise L. McCarthy
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K060780

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